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The use of prostate-specific antigen mass ratio in prostate cancer

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Abstract
Aim: Our goal in this study is to investigate the use and advantage of prostate-specific antigen mass ratio (PSAMR) in prostate cancer.
Material and Methods: Data of patients who underwent prostate biopsy were reviewed prospectively. Body mass index and PSAMR were calculated using height, weight, prostate-specific antigen (PSA) and prostate volume. Patients were divided into benign and prostate cancer. Subgroups were formed according to body mass index. The area under the curve of PSAMR was compared with PSA.
Results: One hundred seventy-one patients were included in the study; 72% of patients were benign and 28% were prostate cancer; 45% of patients were overweight and 20% were obese. PSAMR cut-off value was calculated as 0.37 µg/mL. PSAMR was statistically significant higher than PSA in all patients and subgroups for prostate cancer in area under the curve of receiver operating characteristic analysis.
Discussion: PSAMR avoids unnecessary biopsy by 42%. Especially in overweight and obese patients, PSAMR was found to be statistically significant than PSA for indication of biopsy and prostate cancer diagnosis. This study is the only one in the literature with a high obesity rate.

Keywords
Obesity, Prostate Biopsy, Prostate Cancer

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Introduction

Prostate-specific antigen (PSA) has been used as an adjunct test for screening and diagnosis. Due to its organ-specific nature, the serum level of PSA increases in some cases. These include prostate massage, prostate biopsy, urethral instrumentation, inflammation, trauma and benign prostatic hyperplasia [1]. It is still controversial to mention the cut-off value of PSA. Studies have been conducted to obtain an age-related cut-off for PSA that increases with aging [2]. Free PSA, free prostate-specific antigen percentage, PSA density (PSAD), transition zone PSA density, PSA velocity and PSA doubling time were discovered to detect localized disease and to identify patients who would benefit from curative treatment, but there were insufficient data to replace PSA [3].

Obesity increases the risk of prostate cancer (PCa). Every 5 kg/m2 increase in body mass index (BMI) increases the risk of PCa by 1.05 times [4]. Obesity was found to be a low risk factor for low-risk PCa and a high risk factor for high-risk PCa [5, 6]. Interestingly, early-onset obesity was associated with aggressive PCa, whereas it was found to be poorly associated with late-onset obesity [7].

Obesity is known to cause an increase in the amount of both total and intravascular fluid [8, 9]. It was concluded that PSA was inversely proportional to BMI and measured as low due to hemodilution [10-15]. Prostate-specific antigen mass ratio (PSAMR) is thought to eliminate the hemodilutional effects [16-19]. In addition, PSAMR values have been shown to be unaffected by obesity, metabolic syndrome, and insulin resistance [9, 11, 12, 14]. With this aspect, PSAMR is considered as an alternative to PSA and PSA derivatives, which are used in the diagnosis of PCa and which can give different results due to non-cancerous diseases.

The aim of this study was to investigate the usage of PSAMR in the diagnosis of PCa, whether it has a positive predictive value for individuals with high BMI and its superiority to PSA.

Material and Methods

The study was initiated after obtaining approval from the local ethics committee (Committee's reference number: 2015/745). Patients whose first prostate biopsy was planned in our clinic were included in the study after receiving informed consent forms. Age, PSA, free PSA, height, body weight, BMI, body surface area and plasma volume were recorded, prospectively. Routine 12-quadrant prostate biopsies were performed with a transrectal procedure in the left lateral decubitus position after local anesthesia infiltration. Prostate volume (PV) of patients was calculated by an ellipsoid formula using transrectal ultrasonography (TRUS) during the biopsy. PSAD and PSAMR values were calculated.

Prostate biopsy was planned for patients with suspected digital rectal examination (DRE) findings or PSA ≥ 2.5 ng/mL for those aged younger than 60 years and PSA ≥ 4 ng/mL for those older than 60 years.

Patients with PSA values greater than 20 ng/mL were excluded because of locally advanced or metastatic disease. We excluded from the study diseases and conditions that increase PSA (urinary tract infections, catheterisation, traumatic rectal examination). Patients who received medical treatment, minimally invasive or surgical treatment for benign prostate hyperplasia were excluded from the study because of the effect on PV. Patients who received systemic chemotherapy or radiotherapy were excluded. Patients using glucocorticoids and mineralocorticoids, heart and kidney failure, malabsorption and short-bowel syndrome, inflammatory bowel disease, chronic diarrhea and bowel resection were excluded from the study because of affecting fluid and electrolyte distribution and excretion.

Clinical variables were calculated as follows.

Body Surface Area (m2) = Body weight (kg)0,425 x length (cm)0,725 x 0.007184

Plasma Volume (L) = Body surface area (m2) x 1.67

Prostate Specific Antigen Density = PSA (ng/mL) / prostate volume (mL)

Prostate Specific Antigen Mass Ratio (µg/mL) = PSA (ng/mL) x plasma volume (L) / prostate volume (mL)

Patients were divided into benign groups (BG) and prostate cancer groups (CaG) according to pathology results. Patients were divided into subgroups as BMI < 25 kg/m2 of normal weight, 25 to 29.9 kg/m2 of overweight and BMI ≥ 30 kg/m2 of obese. Age, BMI, PV, PSA, PSAD and PSAMR values of the groups and subgroups were compared. BMI, PSA and PSAMR were compared with the Gleason score. Receiver operating characteristic curve (ROC) of PSA and PSAMR values were prepared in all patients and subgroups. The area under the curve (AUC) values of PSA and PSAMR were compared. Sensitivity and specificity analyzes were performed in all patients and subgroups for PSAMR. The cut-off value of PSAMR was calculated for diagnosis of PCa. The rates of patients who were indicated for biopsy and who would not need biopsy were calculated, when PSAMR was used instead of PSA for age.

PASW Statistics 18.0.0 (SBAS Hong Kong Headquarters, HK) was used for statistical analysis. Pearson's test, Anova test and Student's t-test were used for variables with normal distribution; Spearman's rho, Chi-square, Kruskal Wallis, and Mann-Whitney U tests were used for variables not showing normal distribution. MedCalc software (MedCalc Software Ltd, Ostend, Belgium) was used for ROC analysis comparisons. As a result of statistical analysis, $p < 0.05$ was considered significant.

Results

One hundred seventy-one patients were included in the study. The number and proportion of patients in the groups and subgroups, relation of descriptive statistics and variables with groups and subgroups are shown in Table 1. The incidence of PCa among subgroups according to BMI was not statistically significant ($p = 0.638$). BMI and age were higher in the CaG but not statistically significant. In the BG, the age of the obese subgroup was lower and statistically significant ($p = 0.022$). PV was lower and statistically significant in the CaG and in all subgroups within the PCa ($p = 0.002$). In addition, PV in obese subgroup was high and statistically significant in both BG and CaG, respectively ($p = 0.014$, $p = 0.046$). PSA was found to be significantly higher only in the CaG ($p = 0.015$). PSA was found to be high in patients with PCa in subgroups but not statistically significant. PSAD was found to be high and statistically significant in all patients, normal weight, overweight and

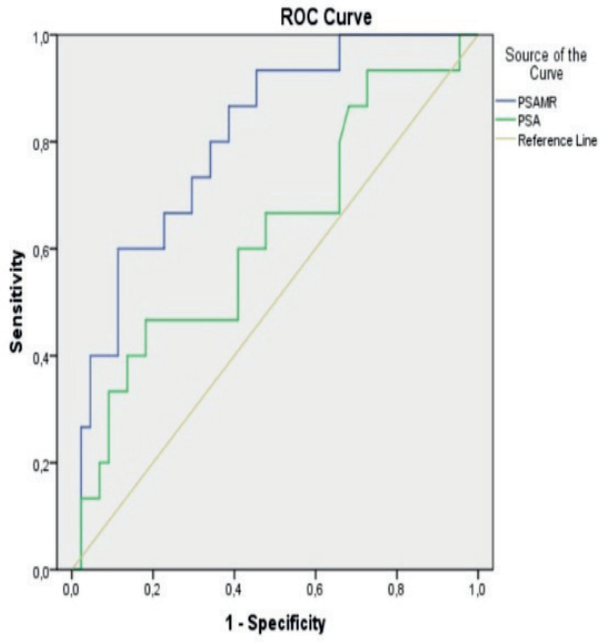

Figure 1. ROC curve of PSAMR and PSA in normal weight subgroup, ROC curve and AUC of PSAMR is higher and statistically significant.

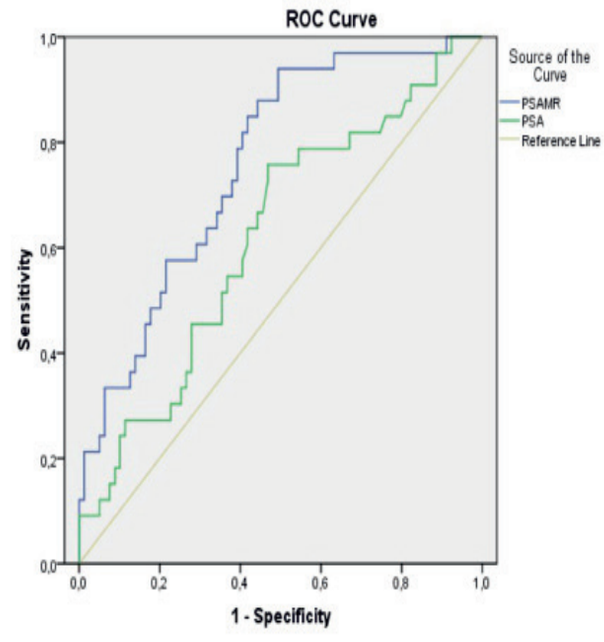

Figure 2. ROC curve of PSAMR and PSA in overweight + obese combined subgroup, ROC curve and AUC of PSAMR is higher and statistically significant.

Table 1. Baseline characteristics, relationships between subgroups and variables

		Total	BG	CaG	p
BMI (kg/m2) (x ± SD) Subgroups n (%)	Total	26.90 ± 4.14	26.75 ± 4.10	27.27 ± 4.26	0.463
	Normal Weight	59 (35)	44 (26)	15 (9)	-
	Overweight	77 (45)	56 (33)	21 (12)	-
	Obese	35 (20)	23 (13)	12 (7)	-
	p	-	-	0.638	
Age (year) (x± SD)	Total	64.11 ± 6.65	63.50 ± 5.90	65.65 ± 8.13	0.101
	Normal Weight	-	64.41 ± 5.52	67.67 ± 7.72	-
	Overweight	-	64.04 ± 5.49	65.10 ± 9.38	-
	Obese	-	60.48 ± 6.80	64.08 ± 6.13	-
	p	-	0.022	0.490	-
Prostate Volume (mL) (Median 25-75)	Total	46 (33 - 68)	51 (39 - 75)	34.50 (27 – 46.75)	<0.001
	Normal Weight	-	44.50 (34.50 - 64)	27 (25 - 32)	0.002
	Overweight	-	50.75 (38.38 – 74.75)	36 (26 - 47)	0.002
	Obese	-	72 (46 - 83)	39 (35 – 55.25)	0.002
	p	-	0,014	0,046	-
PSA (ng/mL) (Median 25 - 75)	Total	7.20 (5.28 - 9.72)	6.7 (5.16 – 9.50)	8.23 (5.79 – 12.34)	0.015
	Normal Weight	-	7.01 (4.92 – 9.36)	7.50 (5.53 – 12.57)	0.141
	Overweight	-	6.23 (5.07 – 10.49)	9.08 (5.99 – 13.05)	0.070
	Obese	-	6.58 (5.83 – 8.70)	8.23 (6.79 – 9.57)	0.237
PSAD (Median 25 - 75)	Total	0.16 (0.11 - 0.24)	0.13 (0.09 – 0.20)	0.24 (0.15 – 0.33)	<0.001
	Normal Weight	-	0.14 (0.11 – 0.21)	0.25 (0.19 – 0.44)	0.001
	Overweight	-	0.12 (0.08 – 0.22)	0.24 (0.15 – 0.41)	<0.001
	Obese	-	0.10 (0.08 – 0.16)	0.21 (0.12 – 0.24)	0.005
PSAMR (µg/mL) (Median 25 - 75)	Total	0.467 (0.31 - 0.77)	0.40 (0.28 – 0.61)	0.76 (0.48 – 1.10)	<0.001
	Normal Weight	-	0.44 (0.31 – 0.61)	0.79 (0.54 – 1.47)	<0.001
	Overweight	-	0.38 (0.27 – 0.72)	0.71 (0.46 – 1.33)	<0.001
	Obese	-	0.32 (0.28 – 0.55)	0.73 (0.42 – 0.93)	0.006

BG: benign group; CaG: prostate cancer group; BMI: body mass index; SD: standard deviation; PSA: prostate- specific antigen; PSAD: prostate- specific antigen density; PSAMR: prostate- specific antigen mass ratio

Table 2. Correlations of BMI, PSA, and PSAMR with pathological grade

	Gleason 6	Gleason 7	Gleason 8	p
BMI (kg/m2) (x ± SD)	27.24 ± 4.53	27.29 ± 4.01	27.38 ± 4.00	0.997
PSA (ng/mL) (x ± SD)	8.28 ± 3.41	11.76 ± 5.17	9.19 ± 3.62	0.057
PSAMR (µg/mL) (x ± SD)	0.89 ± 0.80	1.25 ± 0.69	0.67 ± 0.19	0.132

BMI: body mass index; PSA: prostate-specific antigen; PSAMR: prostate- specific antigen mass ratio; SD: standard deviation

Table 3. Specificity, sensitivity, cut-off and AUC values of PSA and PSAMR for Pca diagnosis

		PSA	PSAMR	MedCalc* p
Total	Specificity	%51.2	%55.3	-
	Sensitivity	%72.9	%87.5	-
	Cut-off (µg/mL)	-	0.44	-
	AUC	0.619	0.770	-
	p	0.015	<0.001	<0.001
Normal weight	Specificity	82%	89%	-
	Sensitivity	47%	60%	-
	Cut-off (µg/mL)	-	0.79	-
	AUC	0.628	0.808	-
	p	0.141	<0.001	<0.023
Overweight	Specificity	50%	57%	-
	Sensitivity	76%	91%	-
	Cut-off (µg/mL)	-	0.44	-
	p	0.070	<0.001	-
Obese	Specificity	57%	91%	-
	Sensitivity	83%	67%	-
	Cut-off (µg/mL)	-	0.65	-
	p	0.237	0.006	-
Overweight	Specificity	53%	50%	-
Obese	Sensitivity	76%	94%	-
Combined	Cut-off (µg/mL)	-	0.37	-
Subgroup	AUC	0.620	0.759	-
	p	0.046	<0.001	0.001

*Statistical software with AUC comparison. AUC: area of under curve; PSA: prostate-specific antigen, PSAMR: prostate-specific antigen mass ratio

obese subgroups, in CaG, respectively ($p < 0.001$, $p = 0.001$, $p < 0.001$, $p = 0.005$). PSAMR was found to be high and statistically significant in all patients, normal weight, overweight and obese subgroups, in CaG, respectively ($p < 0.001$, $p < 0.001$, $p < 0.001$, $p = 0.006$).

Only Gleason scores 6, 7 and 8 PCa were detected. The Gleason scores of 9 and 10 were not detected. There was no correlation between Gleason score and BMI, PSA and PSAMR (Table 2).

Specificity, sensitivity, AUC calculations of PSA and PSAMR, and PSAMR cut-off were performed for groups and subgroups and are shown in Table 3. PSA was significantly higher only in the CaG ($p = 0.015$). PSA was higher in patients with PCa when evaluated separately in normal weight, overweight and obese subgroups, but not statistically significant. However, PSAMR was high and statistically significant in all patients and all subgroups with PCa. AUC of PSAMR was higher and statistically significant in all patients and subgroups in patients with PCa than AUC of PSA. In this study, PSA cut-off was not specified because PSA level was considered for age. In overweight and obese subgroups, the number of patients was low and ROC curve results were similar. Therefore, overweight and obese subgroups were combined for PSAMR cutoff and AUC calculation. In the combined overweight + obese subgroup, the PSAMR cut-off value was 0.37 µg/mL and it was shown in Table 3. The AUC of PSAMR and PSA were compared. The AUC of PSAMR for PCa was high and statistically significant in the combined normal weight and overweight + obese subgroup, respectively (MedCalc $p < 0.023$, MedCalc $p = 0.001$), (Figure 1, 2).

Prostate biopsy was performed in 165 patients who had increased PSA for age and 6 patients with suspicious DRE findings. One hundred thirteen of 171 patients would have a biopsy when PSAMR at a cut-off of 0.37 µg/mL was used instead of PSA for age. If PSAMR was used for biopsy indication instead of PSA, there would have been 3 patients with undetected PCa and they had active surveillance criteria (Gleason 6 prostate adenocarcinoma, PSA < 10 ng/mL).

Discussion

Obesity was detected in 31.2% of women and young people especially, in the TURDEP II study in Turkey. In our study, 35% of all patients were of normal weight, 45% were overweight and 20% were obese. This rate is lower in our study because it was performed in patients older than 45 years. It is thought that the prevalence of obesity will increase over the years, including urologic patients [20]. In the BG, the mean age decreased with increasing BMI and it was statistically significant ($p = 0.022$). However, BMI increase with age was not observed in the CaG ($p = 0.490$). Although the mean age was higher in the CaG, it was not statistically significant ($p = 0.101$). It is thought to have prevented the age difference between the subgroups because there were fewer young patients in the CaG.

The incidence of obesity in the BG was higher at younger ages, which is consistent with the literature, but the reason for the statistical insignificance in the CaG was the effect of the number of patients included in the study. Further studies with large series are needed in the following years.

An increase of PV with increasing BMI has been shown in previous studies [9, 11-13, 21]. In this study, PV is high and statistically significant in overweight and obese patients in BG and CaG, respectively. Because of the inclusion of early-stage patients with PCa, PV is thought to be low in PCa patients. Obesity has been shown to increase the amount of serum estradiol and insulin, alter sex hormone-binding globulin metabolism, and consequently reduce the amount of free testosterone [15]. These studies help explain why PV is high in individuals with a high BMI.

PSAD was found to be high for PCa in all subgroups and statistically significant (Table 1). However, PSAMR and PSAD have not been compared because, although PSAD corrects this confusion in some sense, it does not eliminate the effect of obesity [13, 22-24]. Correlation between the Gleason score and BMI, PSA and PSAMR is not statistically significant. We thought that this result was achieved because, methodologically, the patients who could benefit from curative treatment were included in the study.

In the second biopsy, the probability of cancer detection increases by 1.038 in PSA height and by 3.449 in PSAMR height. It was shown that 59.6% of unnecessary biopsies were avoided with PSAMR and PSAMR was shown to be superior to other PSA derivatives in making a second biopsy decision. The study has been criticized for not including different races [17]. In another study, 0.4 µg/mL was accepted as the cut-off value for PSAMR, and a high risk for biochemical recurrence was shown above this value [18]. According to the results of TURDEP II study, the BMI of patients will increase in the following years, and it may be thought that there will be more problems in measuring serum markers due to dilutional effects. It is thought that the new PSA cut-off value for obese patients would not provide accurate results and would increase the number of unnecessary biopsies [16].

PSAMR is thought to be a more stable and usable parameter in obese patients. In our study, the positive predictive value of PSAMR in CaG was higher than PSA and it was statistically significant. The data of our study are similar to the largest study on this subject, but the fact that the proportion of obese people in South Korea is less than 2% was negatively criticized by the author [19]. Our study was conducted with a heterogeneous population consisting of different ethnicities, races, 45% overweight and 20% obese. Our study is the only study with a high rate of overweight and obese patients compared to previous studies.

In the BG, there were 117 patients with high PSA and underwent biopsy. Using PSAMR, a biopsy would have been performed for 68 patients and 49 patients (42%) would have been protected from the unnecessary biopsy. Three out of 48 PCa patients would not have been detected if PSAMR was used instead of PSA. It was found that they had active surveillance criteria, when the data of these patients were examined. Patients can be protected not only from biopsy but also from overtreatment, with the use of PSAMR. Furthermore, the prevalence of obesity is increasing. PSAMR may be more useful than PSA to detect PCa at an early stage, in people with high BMI [20].

Conclusion

PSAMR can be used as indication criteria for prostate biopsy. Especially in overweight and obese patients, PSAMR is more predictive than PSA. Although the superiority of PSAMR over PSAD has not been demonstrated, PSAMR is more useful than PSA. It also avoids unnecessary biopsy by 42%. Our study should be supported by large prospective randomized controlled trials.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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